PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
UTILITY PATENT APPLICATION TRANSMITTAL

Attorney Docket No.: P-8609
Express Mail No.: **EL 191398358 US**

First Named Inventor or Application Identifier: Harper et al.
Title: Hydrophobic Vent Incorporated into Cerebral Spinal Fluid Drainage Chamber

CERTIFICATE UNDER 37 CFR SECTION 1 10· I hereby certify that this New Application Transmittal and the documents referred to as enclosed therein are being deposited with the United States Postal Service, in an envelope address "EXPRESS **EL 191398358 US** addressed to Box Patent Application, Commissioner of Patents and Trademarks, Washington, D.C. 20231, on this March 11, 1999

Juanita I Traufler
Printed Name

Juanita I. Traufler
Signature

BOX PATENT APPLICATION
Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

We are transmitting the following:

X **Patent Application Transmittal**
X **Specification**
Total Pages: 15 (cover/title page 1 sheet; specification 12 sheets; claims 1 sheets; abstract 1 sheet)
X **Drawings**
Total Sheets: 4 (_ formal; X informal)
X **Combined Declaration and Power of Attorney: (Unsigned)**
- X Newly executed
- _ Copy from prior application
- _ Deletion of inventor(s) -- signed statement attached deleting inventor(s) named in the prior application (37 CFR 1.63(d)(2) and 1.33(b)
- _ Incorporation by reference -- *The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied above is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference herein.*

_ **Accompanying application parts:**
- _ Notification of filing a _ Continuation _ Divisional _ Continuation-in-Part
- _ Assignment of the invention to Medtronic, Inc.
- _ Assignment cover sheet
- _ Information Disclosure Statement
- _ PTO Form 1449
- _ Copies of IDS citations
- _ Preliminary Amendment
- _ A copy of the Petition or Condition Petition for Extension of Time in the prior application
- X Return postcard

IF A CONTINUING APPLICATION:

_ Continuation _ Divisional _ Continuation-in-Part of prior application no. __.

_ Amend the specification by inserting before the first line the sentence: This application is a _ Continuation _ Divisional _ Continuation-in-Part of application number _ filed _.

_ Cancel in this application original claims _ of the prior application before calculating the filing fee. (At least one of the original independent claims must be retained for filing purposes.)

_ The prior application is assigned of record to Medtronic, Inc.

__ The Power of Attorney in the prior application is to: _.

_ This application claims the benefit of U.S. Provisional Application(s) Serial No. _filed _____.

X Address all future correspondence to:

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FEE CALCULATION

	No. Of Claims Filed	Claims Included in Base Fee	No. Of Extra Claims	Rate	Fee
Total Claims	1	20 =		x $ 22	$ 00.00
Independent Claims	1	3 =		x $ 82	$ 00.00
Multiple Dependent Claim(s)		0 =		+ $ 270	
Basic Filing Fee			0		$760.00
				TOTAL	**$760.00**

X Charge Deposit Account No. 13-2546 the sum of $760.00 (Filing Fee) and $0 for Assignment recordation fee for a total of **$760.00**

X The Commissioner is hereby authorized to charge any fees which may be required under 37 CFR 1.16 and 1.17, or credit any overpayment to Deposit Account No. 13-2546. A duplicate of this transmittal is enclosed.

3/11/99
Date

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HYDROPHOBIC VENT INCORPORATED INTO CEREBRAL SPINAL FLUID DRAINAGE CHAMBER

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to a device for draining excess cerebral spinal fluid from a patient's brain and more particularly relates to a device for venting a rigid drip chamber used to drain excessive cerebral spinal fluid (CSF) from a patient's brain.

2. Brief Description of the Prior Art

A typical adult has a total of about 120 - 150 cc of CSF with about 40 cc in ventricles in the brain. A typical adult also produces about 400 - 500 cc/day of CSF, all of which is reabsorbed into the blood stream on a continuous basis. CSF is comprised primarily of water but also includes small amounts of minerals and proteins. Occasionally, blood is present in CSF. This often occurs with trauma to the brain or as a result of other conditions that cause hydrocephalus.

Sometimes, the brain produces excess CSF. Two common causes of the excess production of CSF are hydrocephalus and brain trauma although there are many other causes. Hydrocephalus is a condition of excessive accumulation of CSF in the ventricles or brain tissue. Hydrocephalus can result from genetic conditions or from trauma to the brain. Brain trauma often results from head injuries or other accidents.

Excessive accumulation of CSF, due to hydrocephalus, brain trauma or other causes, manifests itself as increased pressure within the brain. Whatever

the cause, over time, this increased CSF pressure causes damage to the brain tissue. It has been found that relieving the CSF pressure is therapeutically beneficial. This is usually done by draining CSF from the ventricles.

Patients with hydrocephalus or head trauma often continue to produce excess CSF, at least over some time period. Therefore, it is often desirable to continuously drain excess CSF to maintain normal CSF pressure in the brain.

Examples of systems to continuously drain excess CSF are the Becker System® and the EDM Drainage System® made and sold by Medtronic - PS Medical of Goleta, California. Such a device is shown in Figures 1 through 3. In the Figures, the drainage system is shown generally labeled 10. The system includes a rigid drip chamber 12 and a drainage bag 14. A stopcock 16 connects drip chamber 12 to drainage bag 14.

Drip chamber 12 is made of a generally cylindrical, rigid tube 18, an inlet manifold 20 and an outlet manifold 22. Inlet manifold 20 has an inlet 24 and a vent 26. Inlet 24 is connected through tubing 28 to a ventricular catheter (not shown) placed in a patient's head that drains CSF from the patient's ventricle. Outlet manifold 22 has an outlet 30 that is connected to stopcock 16.

Vent 26 is formed by placing a porous material 32 across an opening 34 in a housing 36. Housing 36 is connected to inlet manifold 20 through a connecting tube 38. In this way, vent 26 is fluidly connected to drip chamber 12 through connecting tube 38.

Another example of a system to continuously drain excess CSF is shown in US Patent No. 4,731,056 issued to William S. Tremulis on March 15, 1988 and entitled "External Drainage Antisiphon Device." A further such system is disclosed in US Patent No. 5,772,625 issued to John A. Krueger, Kevin M. Jaeger and Helmut W. C. Rosenberg on June 30, 1998 and entitled "External Drainage Shunt."

All of these prior art systems have rigid chambers to collect and measure the accumulation of CSF drained from the patient. In these prior art systems, it is necessary to vent the rigid drip chambers at the top of the chamber to allow the passage of air in and out of the chamber as cerebrospinal fluid (CSF) moves in and out.

Patients with hydrocephalus that are being treated by draining excess CSF through the use of a drainage system including a drip chamber are often moved from place to place. During movement, the drip chamber is often moved from its substantially vertical alignment and is laid flat in a substantially horizontal orientation.

One current industry practice attempts to prevent contact of the vent by CSF by placing the vent physically away from the inside of the chamber. The venting is typically accomplished by placing a vent on the outside of the top of the chamber. The 26 vent is typically fluidly connected to the inside of the drip chamber 12 through a relatively narrow tube or channel. When the system is laid flat, CSF may enter the tube or channel that connects the vent 26 to the inside of

the drip chamber 12. Then, when the system is raised to vertical, the CSF may not drain from the tube or channel. Consequently, an "airlock" is formed. As a result, air often cannot leave or enter the drip chamber 12.

Another cause of preventing air from moving in or out of the drip chamber 12 occurs in systems where the vent 26 is attached directly to drip chamber 12 but is made of a hydrophilic material or a material that is not sufficiently hydrophobic. The vent 26 being "hydrophilic" means that the vent is made of material that preferentially absorbs water. Not being sufficiently hydrophobic means that the material, while exhibiting some tendency to resist water, never the less has some tendency to attract and retain water.

A major component of CSF is water. In a vent that is made of hydrophilic material or material that is not sufficiently hydrophobic, when the CSF comes into contact with the vent 26 as a result of the drip chamber 12 being laid on its side or being agitated, the CSF is absorbed into and "plugs" the vent 26. Plugging the vent means that air cannot pass across the vent so that the "venting" function cannot be accomplished.

This lack of air movement across the vent 26 can cause two problems depending on whether the air is blocked from moving into or out of the drip chamber 12. If air is prevented from moving out of the drip chamber 12, an "effective airlock" is formed resulting in underdrainage of CSF. If air is prevented from moving into the drip chamber 12 as CSF is drained out of drip chamber 12

into drainage bag 14, a siphon effect will be created leading to overdrainage of CSF.

When water contacts a hydrophilic material or a materiel not sufficiently hydrophilic, a condition called "wetting" results. This means that air is prevented from flowing through the material. Components of CSF in addition to water reduce the surface tension of the fluid. This compounds the "wetting" effect and makes the vent 26 more likely to be plugged by contact with the CSF than it would be with contact with water alone. This "wetting" problem is even more compounded when the CSF that contacts the vent has blood in it. The blood acts as a surfactant which increases the plugging of the material of the vent. As a result, even a small amount of blood in the CSF can cause the vent to plug rapidly if it contacts the hydrophilic vent material.

If air cannot leave the chamber, any additional fluid entering the chamber must compress the air already in the chamber. As a result, the CSF pressure inside the patient's head must increase beyond desired levels to continue to push the fluid into the chamber. The increased cranial pressure results in underdrainage of CSF and can lead to coma and death.

Another problem occurs when air cannot enter the drip chamber 12. In operation, the stopcock 16 is often closed while draining CSF from the brain so that the amount of CSF drained can be accurately measured in the drip chamber 12. After the CSF has been measured, the stopcock 16 is opened and the CSF drains from drip chamber 12 into the drainage bag 14. If air cannot enter the drip

chamber 12 because the vent 26 is plugged, pressure in drip chamber 12 will be reduced as the CSF drains out. As a result, a "siphon" will be created in the tubing 28 as the CSF drains into the drainage bag 14. This siphon will cause additional CSF in the patient's brain to be drained resulting in overdrainage of CSF. Overdrainage of CSF can lead to subdural hematoma and possibly death.

In addition, moving the vent 26 physically away from the drip chamber 12 to prevent contact with CSF, some current systems try to prevent contact between the vent 26 and CSF by having warnings against exposing the drip chamber vent to CSF fluid. Further, some drainage systems provide manually operated shut-offs, such as stopcocks, between the drip chamber 12 and vent 26 to prevent CSF from moving into contact with the vent during transport or at other times when the system is positioned horizontally.

Some current industry devices have vents made of either hydrophilic material or material that is not sufficiently hydrophobic to prevent wetting and plugging.

SUMMARY OF THE INVENTION

The invention comprises several aspects which are each independently useful or which may be combined in a variety of combinations. One aspect of the invention is placing an atmospheric reference vent at or near the top of a rigid drip chamber for draining CSF from a patient. In the preferred embodiment, the vent is placed on the inside of the drip assembly, immediately next to the CSF. Making the vent integral with the top of the drip chamber eliminates the tube or channel

that was present in the prior art devices. This configuration produces a vent that withstands CSF exposure without forming an "airlock" and the corresponding compromised venting capability.

The vent, in another aspect of the invention, is made of a very hydrophobic material, expanded polytetraflouroethylene (e-PTFE). The problem of a hydrophilic vent or a not sufficiently hydrophobic vent getting wet and thereby becoming essentially "blocked" is solved in the present invention by using a very hydrophobic material that eliminates the possibility of blocking due to "wetting" when exposed to CSF or bloody CSF at physiologically significant concentrations and pressures.

In yet another aspect of the invention, the vent is made of a porous material having a pore size that allows air to readily pass through while preventing CSF from passing through. A preferred embodiment of this aspect includes making the vent of expanded polytetraflouroethylene (e-PTFE) with a pore size ranging from about 0.22 μm to about 5.0 μm and more preferable a pore size of about 3 μm. With this pore size, the vent also preferably has a surface area ranging from about 0.8 cm^2 to about 5.0 cm^2. The larger the pore size, the smaller the surface area needs to be to allow adequate venting of air from the drip chamber through the vent. The converse is also true so that vents with smaller pore sizes will need to have larger surface area to allow adequate venting.

In another embodiment of the invention, the vent material is made of a porous material that also prevents microbes from passing through the vent

material into the drip chamber. If microbes get into the drip chamber, it is feared that the microbes could pass out of the drip chamber "upstream" through the tubing to the patient's brains with potentially serious adverse effects. Preventing microbes from entering the drip chamber through the vent material helps to prevent microbial access to the patient's brain. The material of the vent has a pore size of to allow air to pass through it but prevent CSF fluid from passing out of the drip chamber through the material and prevent microbes from entering the drip chamber through the material.

The present invention makes it easier for patients with a need to drain CSF to be treated while they are being transported. With the invention, the CSF drainage system may be laid down horizontally for transport of patient. If CSF is in the drip chamber, it will not adversely affect the venting properties of filter when the system is raised to vertical.

The present invention also has another therapeutic advantage. Because the filter will not be fouled by exposure to CSF or bloody CSF, the vent will always allow the drip chamber to be vented to atmosphere. This will allow the system to have accurate pressure settings for the drainage of CSF from patient.

It is therefore a primary objective of the invention to produce a vent that will not produce an "airlock" if the drip chamber is moved from its substantially vertical orientation to a substantially vertical orientation.

It is another primary objective of the invention to produce a vent that will not be "plugged" or "fouled" by contact with CSF.

It is a further primary objective of the invention to produce a vent that performs its venting function while preventing the ingress of microbes through the vent.

These and other objectives of the invention will be clear to those skilled in the art from the description of the invention set out herein and particularly with reference to the following Detailed Description of the Invention and the corresponding drawings. In the drawings, like elements, wherever shown, are referenced by like reference numbers.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a front view of a prior art CSF drainage system.

Figure 2 is a side view of the system of Figure 1.

Figure 3 is a side cross-sectional view of the vent of the system of Figures 1 and 2.

Figure 4 is a perspective view of a system incorporating the present invention.

Figure 5 is an exploded perspective view of the drip chamber of the system of Figure 4.

Figure 6 is a top view of the inlet manifold of the drip chamber of the system of Figure 4 with the vent in place.

Figure 7 is a top view of the inlet manifold of the drip chamber of the system of Figure 4 without the vent.

Figure 8 is a top view of the vent of the system of Figure 4.

DETAILED DESCRIPTION OF THE INVENTION

A CSF drainage system incorporating the present invention is shown in Figure 4 generally labeled 40. The system includes a rigid drip chamber 12 and a drainage bag 14. A stopcock 16 connects drip chamber 12 to drainage bag 14.

As mentioned, drip chamber 12 is made of a generally cylindrical, rigid tube 18 and includes an outlet manifold 22. Drip chamber 12 also has an inlet manifold 42 that is slightly different from inlet manifold 20. Inlet manifold 42 also has an inlet 24 but has a vent 44 that is different than vent 26 as will be described hereafter. Inlet 24 is connected through tubing 28 to a shunt (not shown) placed in a patient's head that drains CSF from the patient's ventricle. Outlet manifold 22 has an outlet 30 that is connected to stopcock 16.

Vent 44 is formed by covering a hole 46 in inlet manifold 42 with a porous, hydrophobic material 48. Material 48 is adhered to the inside surface of the inlet manifold 42. In the preferred embodiment, material 48 is made of expanded polytetraflouroethylene (ePTFE). The preferred pore size for material 48 ranges from for about 0.22 μm to about 5.0 μm and more preferable has a pore size of about 3 μm. This range of pore sizes allows air molecules to pass through the vent 44 while preventing water or CSF molecules to pass through the vent 44. In addition, this pore size prevents microbes from passing through material 32 into drip chamber 12.

The preferred material for adhering material 48 to inlet manifold 42 is a biocompatible adhesive such as is well understood in the art. Of course, other adhesives, though less desirable, could also be used as well. In addition, other means of adhering the vent to the inlet manifold, including but not limited to a heat staking, ultrasonic welding or RF welding could be used as well.

ePTFE is hydrophobic. In fact, it is the most hydrophobic porous material now known. As a result, it is the most resistive to clogging and loss of low pressure venting properties due to exposure of CSF or CSF with Blood.

In view of the use of the drip chamber 12, the filter must maintain venting properties when fluid is infused into the drip chamber at a nominal rate of 20 ml/hr. In extreme conditions, it may be necessary to vent up to 100 ml/hr. This will allow the drip chamber 12 to properly vent under extreme use conditions. Extreme conditions means that the vent 44 is in contact with CSF containing blood and under high flow rates. In order to properly vent under even extreme use conditions, resistance to CSF flow may not exceed 2.2 cm of H_2O as measured by including the resistance to CSF flow due to resistance in the tubing 28. With the range of pore sizes needed to selectively pass air molecules while inhibiting the passage of water and CSF, the vent also preferably has a surface area ranging from about 0.5 cm^2 to about 5.0 cm^2.

As mentioned above, the blood in CSF is the most severe challenge to the operation of the vent 44. However, the vent 44 should have a pore size sufficient to prevent intrusion of CSF when the drip chamber 12 is internally pressurized to

50 mm of Hg. It is important that the surface area of vent 46 be sufficiently large to still allow adequate venting of drip chamber 12 even if the material 48 of vent 44 has come in contact with CSF containing blood. We have found that for ePTFE material having a pore size of about 3 μm, a surface area greater than about .8 cm^2 will allow proper venting of the drip chamber 12 under even extreme conditions.

In another embodiment of the invention, the porous material 32 of vent 26 shown in Figures 1,2 and 3 and described above is replaced with ePTFE as described above with the corresponding pore size and surface areas also described above.

The present invention has been particularly described in connection with certain specific embodiments thereof. This description has been for the purpose of illustrating the invention and not for the purpose of limiting the invention to the embodiments shown and described. It is further understood that improvements and modifications to the disclosure made herein will occur to those skilled in the art and that such improvements and modifications will still fall within the scope of the invention. It is intended that the invention, as set out in the appended claims, should be construed as broadly as the prior art will permit.

Claims:

1. A drip chamber in a CSF drainage system comprising:

a volume reservoir; and,

a vent in fluid communication with the reservoir, the vent made of expanded polytetraflouroethylene (ePTFE).

APPENDIX

The invention comprises several aspects which are each independently useful or which may be combined in a variety of combinations. One aspect of the invention is placing an atmospheric reference vent at or near the top of a rigid drip chamber for draining CSF from a patient. In the preferred embodiment, the vent is placed on the inside of the drip assembly, immediately next to the CSF. The vent, in another aspect of the invention, is made of a hydrophobic material. In the preferred embodiment, the hydrophilic material is expanded polytetraflouroethylene (e-PTFE). In yet another aspect of the invention, the vent is made of a porous material having a pore size that allows air to readily pass through while preventing CSF from passing through. A preferred embodiment of this aspect includes making the vent of expanded polytetraflouroethylene (e-PTFE) with a pore size ranging from about 0.22 μm to about 5.0 μm and more preferable a pore size of about 3 μm. With this pore size, the vent also preferably has a surface area ranging from about 0.5 cm^2 to about 5.0 cm^2.

Fig. 2

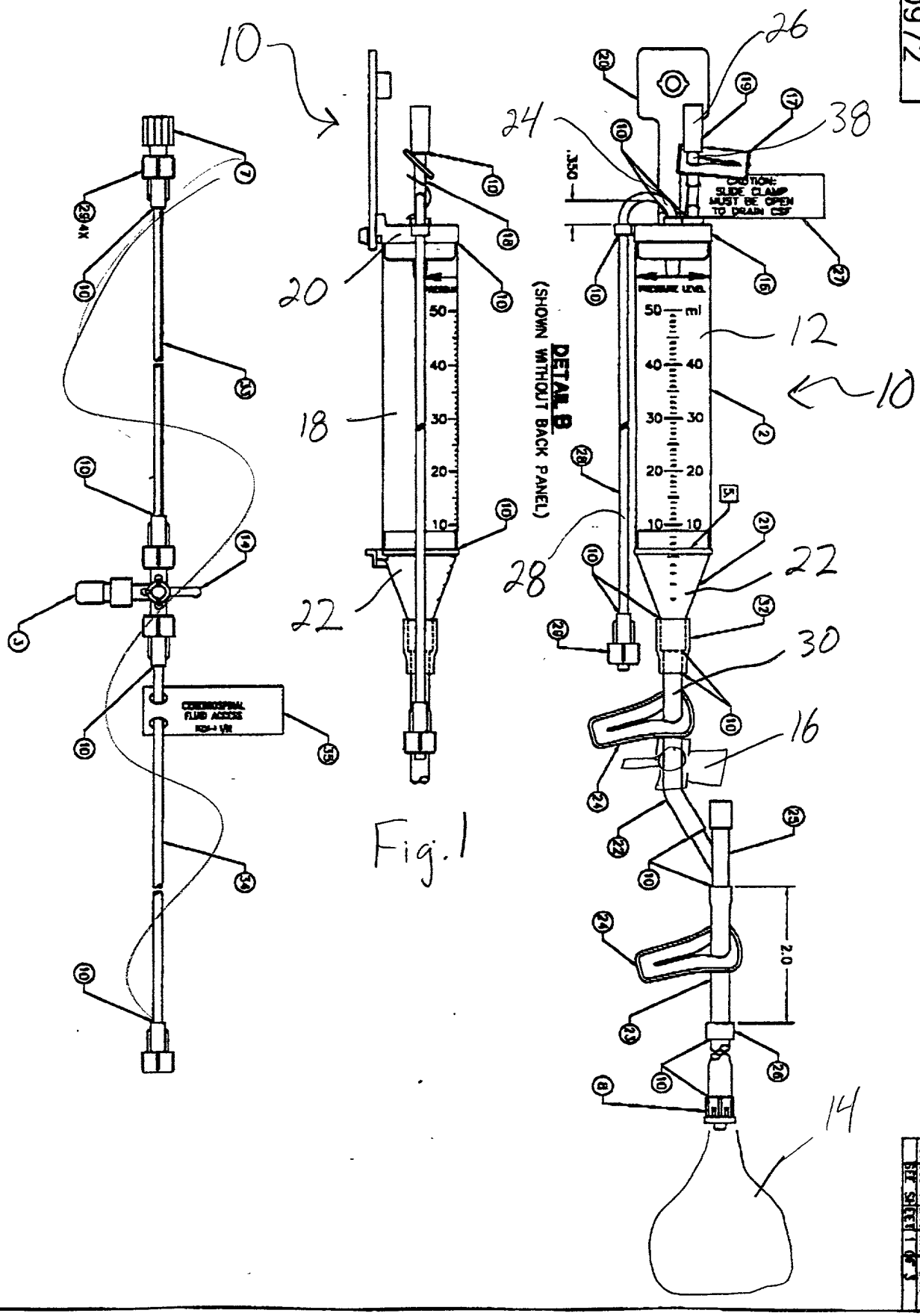


Fig. 1

NOTES: SEE SHEET 1 OF 3

USED ON

ITEM	PART NO.	DESCRIPTION OR MATERIAL	QTY
	46128		

TITLE: ASSEMBLY, BECKER EDMS II

DRAWN: H. WEBER (BP) DATE: 08/11/92
CHK: – DATE: –
APVD: – DATE: –

TOLERANCES ARE: .XX = ± .01 .XXX = ± .003 ANGLES ± 2°

PART NO. 10972-1

Medtronic PS Medical

SCALE: 1/1 SIZE: C SHEET 2 OF 3 REV: E

DRAWING NO. 10972

KEY DOC NO | DRAWN | CHK | DATE

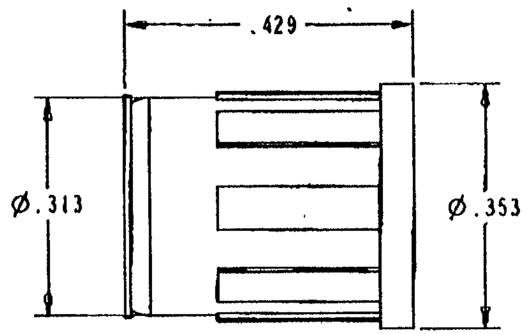
SEE SHEET 1 OF 3

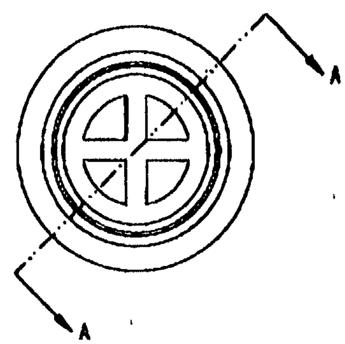
RELEASED 11/14/96

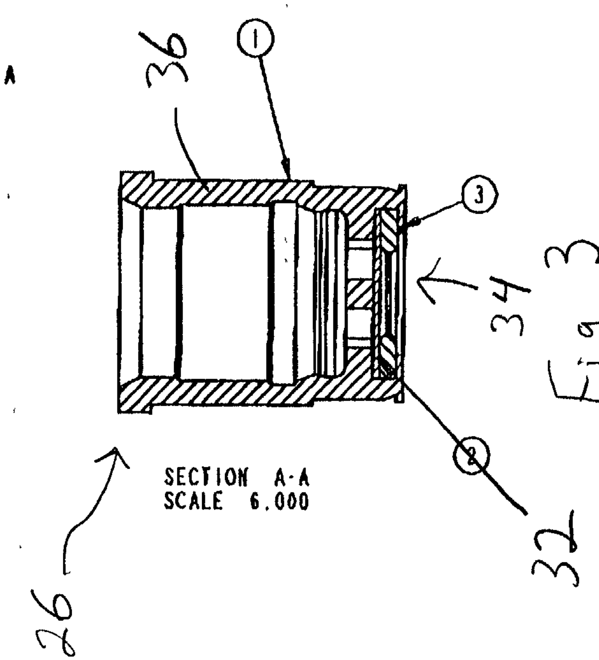
DRAWING NO. 10366 PRO-E

REV	DCO NO	DWN	CHK	DATE
A	5363	JBN	SC	11/15/96

APPROVED SUPPLIER: B. BRAUN
SUPPLIER PART NUMBER: S5002300







SECTION A-A
SCALE 6.000

Fig. 3

6. PACKAGING:
SEALED IN DOUBLE POLYETHYLENE BAGS AND PLACED IN A CARDBOARD BOX.

5. LABELING: PART NO. AND QUANTITY.

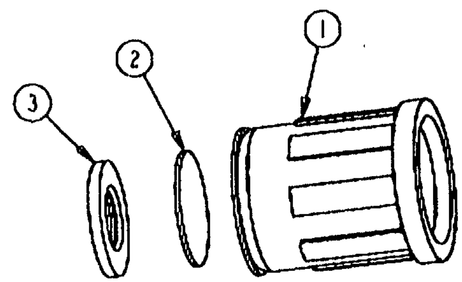
4. PARTICLES AND FIBERS/CLEANLINESS:
NO OIL OR GREASE ON PART.
LOOSE:
PARTICLES: NONE VISIBLE > .025".
FIBERS: NONE VISIBLE > .050" X .005".
EMBEDDED:
PARTICLES: NONE VISIBLE > .020".
FIBERS: NONE VISIBLE > .040" X .005".

3. SURFACE IMPERFECTIONS:
CRACKS, VOIDS OR SHORT SHOTS: NONE.
AIR POCKETS:
OPEN TO SURFACE: NONE.

2. FLASH/BURRS: NONE > .020".

1. GATE STUB: NONE > .015" REMAINING.

NOTES: UNLESS OTHERWISE SPECIFIED



SCALE 4.000

ITEM	PART NO.	DESCRIPTION OR MATERIAL
3	T26795	WASHER (BORG-WARNER ABS RESIN)
2	E01003E	FILTER MEMBRANE (PALLFLEX)
1	5020A	HOUSING (EASTMAN KODAK POLYALLOMER)

TITLE FILTER CAP ASSEMBLY BECKER EDMS

Medtronic

USED ON	
10653-1	
10972-1	

DWN JD MILLER 07/30/96 · DATE 11/13/96 · SCALE 6.000 · SIZE B
CHK · DATE 11/1x/96 · PART NO.: 10366-1 · SHEET 1 OF 1
TOLERANCES ARE: .XX ±, .XXX ± · DIMENSIONS ARE IN INCHES .005 · DWG. NO. 10366 · REV A

09266674.031199

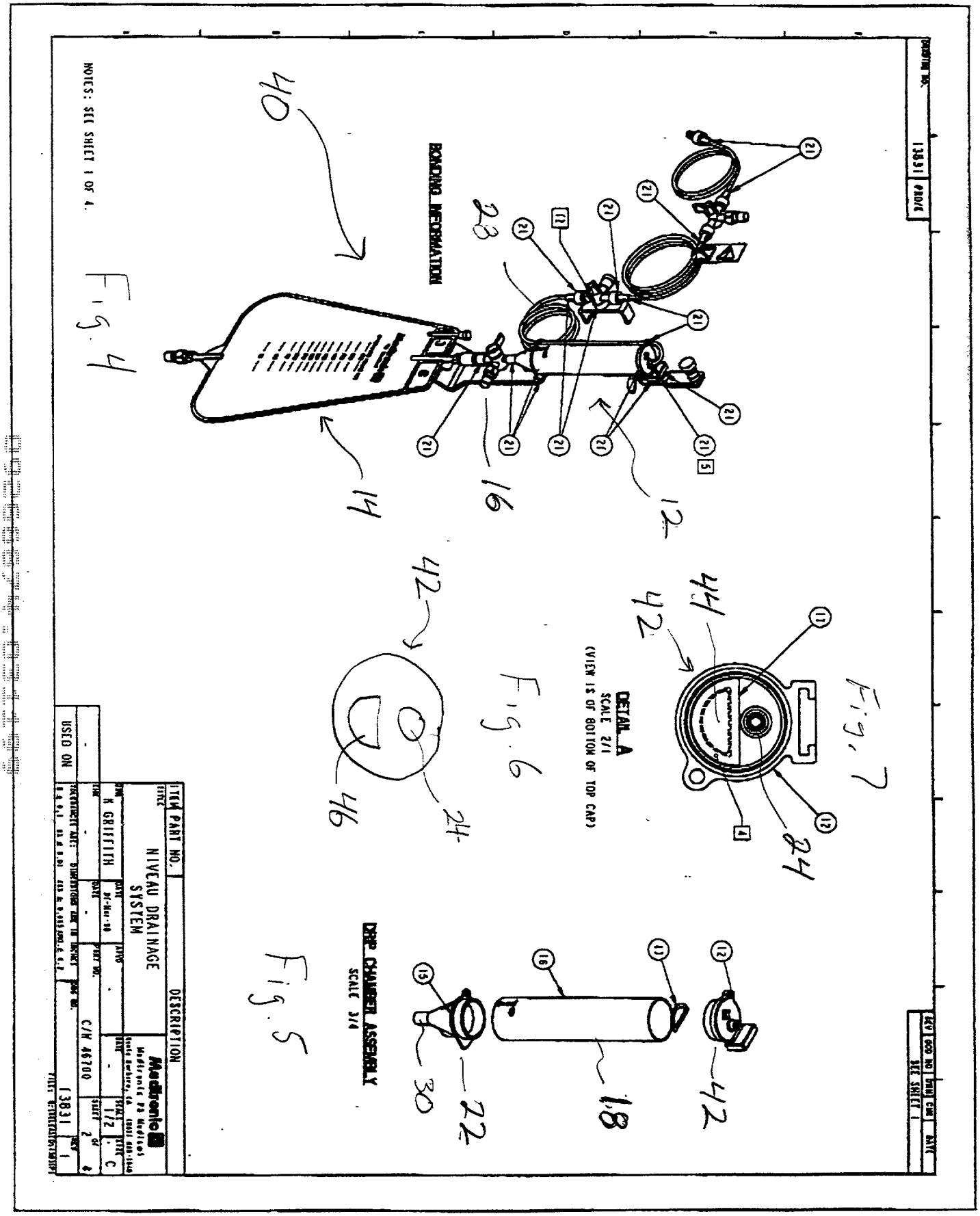


Fig. 4

Fig. 5

Fig. 6

Fig. 7

DWG NO	
13853	PRO/E

APPROVED SUBCONTRACTER: W.L. GORE
PART NUMBER: D30283

REV	DCO NO	DWN	CHK	DATE
2	7856	LH		11/27/98

7. PORE SIZE: 3μm

6. PACKAGING: PACKAGE ON ROLLS WITH 3" MIN. SPOOL DIAMETER. 1 PART ACROSS MAXIMUM, ON NON-OPAQUE CARRIER. SEALED IN DOUBLE POLYETHYLENE BAGS AND PLACED IN SHIPPING CONTAINER TO PREVENT DAMAGE.

5. LABELING: PART NUMBER, QUANTITY AND MANUFACTURER'S LOT NUMBER.

4. PARTICLES AND FIBERS/CLEANLINESS:
NO OIL OR GREASE ON PART.
LOOSE:
PARTICLES: NONE VISIBLE > .025"
FIBERS: NONE VISIBLE > .050" X .005"
EMBEDDED:
PARTICLES: NONE VISIBLE > .010"
FIBERS: NONE VISIBLE > .040" X .005"

3. SURFACE IMPERFECTIONS:
CREASE, TEARS OR OTHER DAMAGE: NONE
ROUGH EDGES: NONE > .010"

2. CERTIFICATION: SUPPLIER TO PROVIDE CERTIFICATION INCLUDING: P.O. NUMBER, MEDTRONIC PS MEDICAL P/N AND REVISION, MANUFACTURERS LOT NUMBER, PORE SIZE AND BUBBLE POINT DATA (MEAN & STANDARD DEVIATION)

1. (■) INDICATES INSPECTION DIMENSION.

NOTES: UNLESS OTHERWISE SPECIFIED.

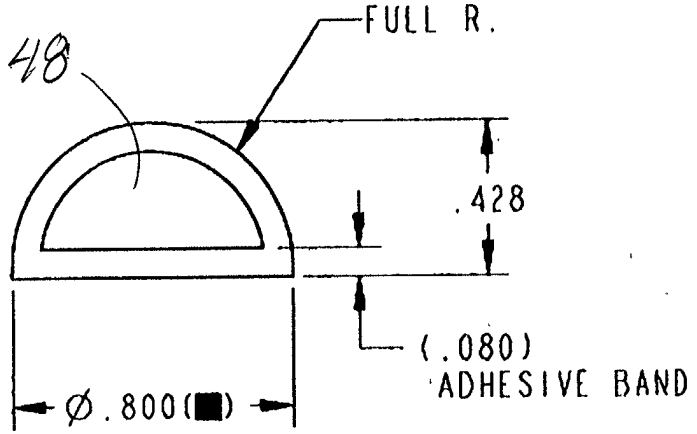


Fig. 8

ITEM	PART NO.	DESCRIPTION OR MATERIAL
-	-----	GA 2000 ACRYIC ADHESIVE
-	-----	PTFE MEMBRANE

TITLE: HYDROPHOBIC VENT, DRIP CHAMBER

Medtronic
Medtronic PS Medical
Santa Barbara, CA (805) 968-1546

DWG	DATE	APVD	DATE	SCALE	SIZE
L. HAMPTON	30-Jul-98		11/27/98	2/1	A
CHK	DATE	PART NO.:		SHEET	OF
	11/25/98	13853-1		1	1

TOLERANCES ARE: DIMENSIONS ARE IN INCHES
XX ± 0.1 XXX ± 0.02 XXXX ± 0.010 ANG ± 2.0

DWG. NO 13853 REV 2

FILE: R \RELEASED\13853P2

USED ON

ATTORNEY DOCKET: P-8609

United States Patent Application

COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that

I verily believe I am the original, first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled **Hydrophobic Vent Incorporated into Cerebral Spinal Fluid Drainage Chamber**

The specification of which
a. X is attached hereto
b. _____ was filed on _____as application serial no. _____ and was amended on _____ (if applicable) (in the case of a PCT-filed application) described and claimed in international no. _____ filed _____ and as amended on _____ (if any), which I have reviewed and for which I solicit a United States patent.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37 Code of Federal Regulations, §1.56(a).[1]

I hereby claim foreign priority benefits under Title 35, United States Code, §119/365 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on the basis of which priority is claimed:

a. x no such applications have been filed.
b. ___ such applications have been filed as follows:

FOREIGN APPLICATION(S), IF ANY, CLAIMING PRIORITY UNDER 35 USC §119

COUNTRY	APPLICATION NUMBER	DATE OF FILING	DATE OF ISSUE

ALL FOREIGN APPLICATIONS, IF ANY, FILED BEFORE THE PRIORITY APPLICATION(S)

COUNTRY	APPLICATION NUMBER	DATE OF FILING	DATE OF ISSUE

I hereby claim the benefit under Title 35, United States Code, §1120/365 of any United States and PCT international application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §156(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

[1] **§ 1.56 Duty of disclosure; fraud, striking or rejection of applications.**
(a) A duty of candor and good faith toward the Patent and Trademark Office rests on the inventor, on each attorney or agent who prepares or prosecutes the application and on every other individual who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application. All such individuals have a duty to disclose to the Office information they are aware of which is material to the examination of the application. Such information is material where there is substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent. The duty is commensurate with the degree of involvement in the preparation or prosecution of the application.

U.S. APPLICATION NUMBER	DATE OF FILING	STATUS (patented, pending, abandoned)

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith:

Harold R. Patton	Reg. No. 22,157	Michael B. Atlass	Reg. No. 30,606
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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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_____ Additional pages for fourth and subsequent inventors attached.

X This Declaration ends with this page.